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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,044

07/30/2003

Benny C. Askew

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08/11/2006

AMGEN INC.

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EXAMINER

SAEED, KAMAL A

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/632,044	Applicant(s) ASKEW ET AL.	
	Examiner Kamal A. Saeed	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12, 14, 67 and 111-134 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-12, 14, 67 and 111-134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/9/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 13, 15-66 and 66-110 have been cancelled. Therefore, claims 2-12, 14, 67 and 111-134 are currently pending in this application.

Information Disclosure Statement

Applicant's Information Disclosure Statements, filed on 09 June 2006 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Amendment and Remarks

Applicant's amendments have overcome the objection of the claims 2-12, 14 and 111-134. as set forth in previous Office Action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicants preserve their right to file a divisional on the non-elected subject matter.

The following Rejections are maintained

Claims 2-12, 14 and 111-134 are rejected under 35 U.S.C 112 first paragraph, because the specification while enabling for a method of treatment specific cancer diseases (claims 111-122), specific cell proliferative disorder (claims 2-12 and 14) and specific diseases treated by the inhibition of serine kinase (claims 123-133), the specification doesn't provide enablement for all cancer diseases and all diseases affected by the inhibition of serine kinase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention commensurate in scope with these claims. The reasons provided in the previous office action is incorporated hereby reference.

Applicant's argument has been fully considered but they were not deemed to be persuasive. The scope of diseases claimed to be treated would thereby include all types of cancer, including such diverse types of cancer as leukemia, sarcoma, malignant lymphoma, breast cancer, prostate cancer, pancreatic cancer, renal cancer, lung cancer etc. The specification teaches a few *in vitro* studies in human cell lines demonstrating the *in vitro* activity and tolerability of the claimed compounds. Given the scope of the many types of cancer, included in **claim 2-12, 14 and 111-122**, their varied etiologies, and the diversity of their patient populations, the specification is insufficient to permit a person skilled in the art to practice a method of treating cancer. Due to unpredictable nature of cancer and the fact that the various types of cancer have different causative agents, involve different cellular mechanisms, and differ in treatment protocol, thus no single compound exists presently that is known to treat all cancers as a blanket therapeutic. Furthermore, the Merck[®] manual currently has many cancer treating agents (over 12000 compounds), yet they are only known to treat one cancer each. Although applicants have cited some references to support their position they were not found to overcome the rejection as discussed above.

Moreover there are so many diseases that are affected by the inhibition of serine/therein kinase. These include cancers, immunodeficiencies and endocrine disorders. The claims encompass all types of serine/thernine kinase mediated diseases, which include diseases known to exist and those that may be discovered in futre and the specification offer no guidance other than an invitation a skilled artisan to perform random trial and error experimentation to try to

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finer if the compounds are suitable therapeutic agents for those diseases. Applicant cites A. Catania et al as state of the art to support the claimed therapeutic activity, however, the reference does not conclusively provide to one of ordinary skill in the art that the compounds disclosed therein would be effective in all types of diseases mediated by serine/threonine kinase.

Therefore **THIS ACTION IS MADE FINAL** . Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:30 AM- 5:00 PM.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet

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e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'K. Saeed', written over a horizontal line.

Kamal Saeed, Ph.D.,
Patent Examiner, AU 1626